

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
18688

NOV 14 2005

In Re Application Of: **Kathryn E. Lawlor et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/525,363	February 23, 2005	Unassigned	23389	Unassigned	5197

Title: **A METHOD OF TREATMENT AND PROPHYLAXIS**

Address to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

37 CFR 1.97(b)

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

37 CFR 1.97(c)

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:
- ☐ the statement specified in 37 CFR 1.97(e);
- OR**
- ☐ the fee set forth in 37 CFR 1.17(p).

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

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Payment of Fee

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of _____ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **19-1013/SSMP** as described below.
- ☐ Charge the amount of _____
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Edward W. Grolz

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Dated: November 10, 2005

Edward W. Grolz

Registration No. 33,705

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Kathryn E. Lawlor et al.	Examiner:	Unassigned
Serial No.:	10/525,363	Art Unit:	Unassigned
Filed:	February 23, 2005	Docket:	18688
For:	A METHOD OF TREATMENT AND PROPHYLAXIS	Dated:	November 10, 2005
		Confirmation No:	5197

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. United States Patent No. 5,420,109 dated May 30, 1995, issued to Suto et al.;

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 10, 2005.

Dated: November 10, 2005


Edward W. Grolz

2. United States Patent No. 5,639,455, dated June 17, 1997, issued to Shimomura et al.;
3. United States Patent Application Publication No. 2002/0141994 dated October 3, 2002, issued to Devalaraja et al.;
4. International Patent Publication No. 95/21864, dated August 17, 1995;
5. International Patent Publication No. 95/21867, dated August 17, 1995;
6. International Patent Publication No. 02/07676, dated January 31, 2002;
7. Bernard, L.A. et al., "Pimecrolimus 1% Cream (Elidel®) For Atopic Dermatitis," *Skin Therapy Letter*. 7(4): 1-3, (2002);
8. Campbell, Ian et al., "The Colony-Stimulating Factors and Collagen-Induced Arthritis: Exacerbation of Disease by M-CSF and G-CSF and Requirement for Endogenous M-CSF," *J. of Leukocyte Bio.* 68: 144-150, (2000);
9. Ghivizzani, Steve C. et al., "Gene Therapy Approaches for Treating Rheumatoid Arthritis," *Clin. Orthopaedics and Related Research*. 379S: S288-S299, (2000);
10. Hermans, Mirjam et al., "Sustained Receptor Activation and Hyperproliferation in Response to Granulocyte Colony-Stimulating Factor (G-CSF) in Mice with a Severe Congenital Neutropenia/Acute Myeloid Leukemia-derived Mutation in the G-CSF Receptor Gene," *J. Exp. Med.* 189(4): 683-691 (1999);
11. Caporali, Roberto et al., "Cyclophosphamide Plus Granulocyte Colony Stimulating Factor (G-CSF) is More Effective than G-CSF Alone in Mobilizing Hemopoietic Progenitor Cells in Severe, Refractory Rheumatoid Arthritis," *Haematologica*. 86(1): 106-107 (2001);
12. Kawamura, Hiroki et al., "Expansion of Extrathymic T Cells as Well as Granulocytes in the Liver and Other Organs of Granulocyte-Colony Stimulating Factor Transgenic Mice: Why They Lost the Ability of Hybrid Resistance," *J. of Immunology*. 162: 5957-5964, (1999);
13. Roessler, Blake J. et al., "Inhibition of Interleukin-1-Induced Effects in Synoviocytes Transduced with the Human IL-1 Receptor Antagonist cDNA Using an Adenoviral Vector," *Human Gene Therapy*. 6: 307-316, (1995); and
14. Saggio, I. et al., "Adenovirus-Mediated Gene Transfer of a Human IL-6 Antagonist," *Gene Therapy*. 4: 839-845, (1997).

Reference numbers 1-3, 7-10 and 12-14 were cited in an International Search Report, dated November 20, 2003, a copy of the search report was filed on February 23, 2005, therefore a copy is not provided. Applicants are submitting copies of reference numbers 7-10 and 12-14.

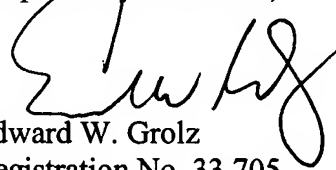
In accordance with the waiver of 37 C.F.R. § 1.98 (a)(2)(i) in effect as of June 30, 2003, applicants are not required to submit copies of the U.S. Patent references (reference numbers 1-3).

Reference numbers 4-6 and 11 were cited in a Supplementary Partial European Search Report dated July 28, 2005. Applicants are submitting a copy of the search report together with a copy of the references. The relevance of these references has been described in the Search Report.

Consideration of this Information Disclosure Statement is respectfully requested, since the art provided may be material to the examination of the present application as defined under 37 C.F.R. §1.56.

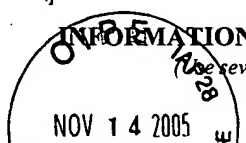
Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. § 1.97(b), no statement or fee is required.

Respectfully submitted,



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Enclosure: Form PTO 1449

<div style="text-align: center;">  <p>INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)</p> </div>	Docket Number (Optional) <div style="text-align: center;">18688</div>	Application Number <div style="text-align: center;">10/525,363</div>
	Applicant(s) <div style="text-align: center;">Kathryn E. Lawlor et al.</div>	
	Filing Date <div style="text-align: center;">February 23, 2005</div>	Group Art Unit <div style="text-align: center;">Unassigned</div>

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5,420,109	5/30/1995	Suto et al.			
		5,639,455	6/17/1997	Shimomura et al.			

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		2002/0141994	10/3/2002	Devalaraja et al.			

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
		95/21864	8/17/1995	WO				
		95/21867	8/17/1995	WO				
		02/07676	1/31/2002	WO				

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		Bernard, L.A. et al., "Pimecrolimus 1% Cream (Elidel) For Atopic Dermatitis," <i>Skin Therapy Letter</i> . 7(4): 1-3, (2002);
		Campbell, Ian et al. "The Colony-Stimulating Factors and Collagen-Induced Arthritis: Exacerbation of Disease by M-CSF and G-CSF and Requirement for Endogenous M-CSF," <i>J. of Leukocyte Bio</i> . 68: 144-150, (2000);

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>		Docket Number (Optional) 18688	Application Number 10/525,363
		Applicant(s) Kathryn E. Lawlor et al.	
		Filing Date February 23, 2005	Group Art Unit Unassigned
*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>		
	Ghivizzani, Steve C. et al., "Gene Therapy Approaches for Treating Rheumatoid Arthritis," <i>Clin. Orthopaedics and Related Research</i> .379S: S288-S299, (2000);		
	Hermans, Mirjam H.A. et al., "Sustained Receptor Activation and Hyperproliferation in Response to Granulocyte Colony-Stimulating Factor (G-CSF) in Mice With a Severe Congenital Neutropenia/Acute Myeloid Leukemia-Derived Mutation in the G-CSF Receptor Gene," <i>J. Exp. Med.</i> 189(4); 683-691 (1999);		
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	Kawamura, Hiroki et al., "Expansion of Extrathymic T Cells as Well as Granulocytes in the Liver and Other Organs of Granulocyte-Colony Stimulating Factor Transgenic Mice: Why They Lost the Ability of Hybrid Resistance," <i>J. of Immunology</i> .162: 5957-5964, (1999);		
	Roessler, Blake J. et al., "Inhibition of Interleukin-1-Induced Effects in Synoviocytes Transduced with the Human IL-1 Receptor Antagonist cDNA Using an Adenoviral Vector," <i>Human Gene Therapy</i> . 6: 307-317, (1995);'and		
	Saggio, L. et al., "Adenovirus-Mediated Gene Transfer of a Human IL-6 Antagonist," <i>Gene Therapy</i> .4: 839-845, (1997).		
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